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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/896,050 | 06/29/2001 | John Ghrayeb | 0148.1102-011 | 1490 |

21005 7590 03/29/2004

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EXAMINER

SCHWADRON, RONALD B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1644

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 09/896,050 | | GHRAYEB ET AL. | |
| | Examiner | | Art Unit | |
| | Ron Schwadron, Ph.D. | | 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,7,13,16,17,19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) 13,16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,7,19,20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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1. Claims 1,4,5,7,19,20 are under consideration.

RESPONSE TO APPLICANTS ARGUMENTS

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1,4,5,7,19,20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that hybridoma producing M-T412 or the cell line producing C128 is required to practice the claimed invention. The claims recite a chimeric antibody which uses the M-T412 variable region. There is no disclosure of the amino acid sequence of the variable region of M-T412, so either the M-T412 antibody or C128 would be required to produce said chimeric antibody. The reproduction of an identical cell line is an extremely unpredictable event. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. The instant specification does not disclose a repeatable process to obtain the hybridoma M-T412 or C128A cell line and it is not apparent if said cells are readily available to the public. Therefore, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of said hybridoma or cell line. See 37 C.F.R. 1.802.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a

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position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. 1.808.

It is noted that the BPAI affirmed a similar deposit requirement based rejection in parent application 07/867100 for claims using the M-T412 variable region in a chimeric antibody.

Regarding applicants comments, applicant has not complied with 37 C.F.R. 1.808 by providing the statement required above. It is also unclear as to what "suitable deposit" means. Applicant should indicate that the cell line producing M-T412 or c128 will be deposited under conditions of the Budapest Treaty.

4. The rejection of claims 1-6 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Oi et al. as evidenced by Taylor et al. as enunciated in the previous Office Action is withdrawn in view of the amended claims and cancellation of claims 2,3,6.

5. The rejection of claims 1-7,19,20 under 35 U.S.C. 103(a) as being unpatentable over Oi et al. in view of Landau et al. or Taylor et al. or Weissenhorn et al. (1996) as enunciated in the previous Office Action is withdrawn in view of the amended claims and cancellation of claims 2,3,6.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 1,4,5,7,19,20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1,4,5,7 are indefinite in the recitation of "antibody M-T412". M-T412 is a laboratory designation which doesn't specifically define the structure of the antibody or necessarily refer to a specific antibody. A preferred substitution is to replace said name with the ATCC deposit number of the hybridoma producing said antibody.

8. Regarding applicants request for rejoinder, there are currently no allowed claims in the instant application.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571 272 0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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GROUP 1800 1644

Ron Schwadron, Ph.D.

Primary Examiner

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